

REMARKS

Applicants appreciate the examiner's statement that claims 161-162, 261-262, 264-265, and 269 are in condition of allowance. Claims 161-162, 166, 261-262, 264-265, and 269 are pending in this application for the Examiner's review and consideration. Claims 163-165, 266-267, and 271-279 have been canceled without prejudice. Applicants fully reserve their rights to prosecute the subject matter of any cancelled claim in one or more continuation, continuation-in-part, or divisional applications.

Claims 165 and 273-279 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. patent No. 5,891,891 to E. Benincasa ("the '891 patent") for the reasons set forth at page 2 of the Office Action. Because claims 165 and 273-279 have been cancelled the rejection is now moot as to those claims.

The Office Action alleges that "[t]he rejection is applicable to method claim 166. Claim 166 recites a method for treating a patient suffering from insomnia by administering a therapeutically effective amount of the zolpidem hemitartrate of claim 161. Claim 161 recites zolpidem hemitartrate Form D characterized by a particular PXR. The Office Action, however, does not set out a prima facie case of anticipation. In fact, the Office Action does not discuss any grounds of anticipation of claim 166 by the prior art. Because claim 161 is allowable and the Office Action does not set out a prima facie case of anticipation against dependent claim 166, applicants contend that the rejection cannot stand and must be withdrawn.

Accordingly, for the reasons discussed above, the rejection of claims 166 under 35 U.S.C. § 102 (b) as anticipated by the '891 patent cannot stand and should be withdrawn.

Claims 264-267, 269, and 271-272 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular, the Office Action alleges that there is no antecedent basis for the terms "monohydrate" or "hemihydrate" in base claim 161. Applicants respectfully traverse.

Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *Solomon v. Kimberly-Clark Corp.* 216 F.3d 1372, 55 U.S.P.Q.2d 1279

(Fed. Cir. 2000) citing *Personalized Media Communications, LLC v. ITC*, 161 F.3d 696, 705, 48 U.S.P.Q.2d 1180, 1888 (Fed. Cir. 1998) (emphasis added). If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Id.* In other words, the definiteness of the claim language must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *Solomon v. Kimberly-Clark Corp.* 216 F.3d 1372, 55 U.S.P.Q.2d 1279 (Fed. Cir. 2000) citing *In re Moore*, 439 F.2d 1232, 169 U.S.P.Q. 236 (CCPA 1971). Additionally, the claims should not be rejected for non-inclusion of additional limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recited such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *See In re Skrivan*, 427 F.2d 801, 806, 166 U.S.P.Q. 85, 88 (C.C.P.A. 1970).

Claim 264 recites “[t]he zolpidem hemitartrate of claim 161, where the zolpidem hemitartrate is a monohydrate.” The specification states that Form D can be a monohydrate or hemiethanolate. *Application*, p.18, line 17. The term “monohydrate” is first introduced in dependent claim 264. Accordingly, the term is appropriately introduced using the term “a.” Moreover, applicants wish to point out that claim 264 has been allowed, thus indicating that the claim has complied with all statutory requirements for patentability. Claim 265 is dependent upon allowed claim 264.

Claim 269 recites “[t]he zolpidem hemitartrate of claim 161, where the zolpidem hemitartrate is a hemiethanolate. The term “hemiethanolate” is first introduced in dependent claim 269. Accordingly, the term is appropriately introduced using the term “a.” Moreover, applicants wish to point out that claim 269 has been allowed, thus indicating that the claim has complied with all statutory requirements for patentability.

Accordingly, for the reasons discussed above, the rejection of claims 264-265, and 269 under 35 U.S.C. § 112, second paragraph, for being indefinite cannot stand and should be withdrawn.

Pending claims 163, 164, 266-267, and 271-278 stand rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement.

Applicants respectfully traverse. Because these claims have been cancelled, the rejection is now moot.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

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